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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,803

01/23/2007

Patrick Soon-Shiong

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09/04/2008

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,803	Applicant(s) SOON-SHIONG ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on May 21, 2008, the applicants have amended claims 55, 56, 59, 60, 63-65, 67, 68, 73, 75-78, 81-83, 85, 87, 88, 93, 95 and 97-100.
2. Claims 55-108 are pending in the application.

Response to Arguments

3. Applicant's arguments filed on May 21, 2008 have been fully considered but they are not persuasive regarding enablement, indefiniteness and obviousness rejections. The applicants have amended claims to overcome all prior art rejections. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the specification is enabling for treating every known cancer in the art. The applicants have not provided any evidence that structurally closely related camptothecin compounds are well known or well established to treat every type of known cancer in the art. There is no teaching or guidance present in the specification regarding any specific mechanism of action of the instant compounds. The instant compounds are novel and therefore, will require undue experimentation to check their efficacy in every known cancer cell line in vitro and hence their utility for treating every known cancer. In regard to indefiniteness rejection, the examiner does not agree with the applicants arguments that the compounds are described fully in the body of claims and therefore, the term --- derivatives--- is definite. It is not clear what is the need of this term if compounds are fully described. This term is not even defined in the specification and can comprise prodrugs, polymorphs, solvates etc. in addition to the compounds which are fully defined. In regard to obviousness rejection, the examiner does not agree with

Art Unit: 1625

the applicant's arguments that Du's reference discloses only synthetic intermediates but does not disclose specific utility of these compounds. The applicant's attention is drawn to first paragraph of the introduction where DB-67 has been mentioned to have broad spectrum of activity against solid tumors. The camptothecin compounds are well known to have utility in treating variety of cancers. The compounds 6-9 disclosed by Du are esters or prodrugs of camptothecin compounds in order to enhance their availability to the blood stream following systemic administration by avoiding their destruction by esterases in the gut. Therefore, it would have been obvious to one skilled in the art to prepare instant diesters by modifying the R group of diesters disclosed by Du with reasonable expectation of success.

Conclusion

4. Rejections under 35 U.S.C. 112, first paragraph and second paragraph as well as under 35 U.S.C. 103(a) are maintained for the reasons of record.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1625

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625